

<b>Case Number:</b>	CM14-0216684		
<b>Date Assigned:</b>	02/10/2015	<b>Date of Injury:</b>	09/15/2010
<b>Decision Date:</b>	05/19/2015	<b>UR Denial Date:</b>	12/12/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/26/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California, Washington

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 30-year-old female who sustained an industrial injury on September 15, 2010. The mechanism of injury was not provided. She has reported right shoulder pain radiating down the arms associated with muscle spasm and has been diagnosed with right shoulder joint derangement, unspecified and status post right carpal tunnel release with residual pain. Treatment has included acupuncture, medications and urine drug screening. The documentation of 11/07/2014 revealed that the injured worker had tenderness to palpation at the supraspinatus insertion site at the levator scapula. The injured worker had tenderness to palpation at the rhomboids in AC joint. The injured worker had decrease range of motion of the shoulder and had a positive Neer impingement sign. The motor strength was 4/5 in all represented muscle groups in the right upper extremity and the reflexes were 2+ in the bilateral upper extremities. There was decreased sensation to pinprick along the course of the median nerve distribution in the right upper extremity. The treatment plan included medications and physiotherapy. On December 12, 2014 Utilization Review non certified synapryn 10mg/1ml oral suspension 500 ml, tabradol 1mg/ml oral suspension 250ml, Deprizine 15 mg/ml oral suspension 250 ml, dicopanal 5 mg/ml oral suspension 150 ml, fanatrex 25 mg/ml oral suspension 420 ml, MRI of the right shoulder, 18 acupuncture treatments for the right shoulder and wrists, and Terocin patches citing the MTUS, ACOEM, and Official Disability Guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Synapryn 10mg/1ml oral suspension 500ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, 94. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Synapryn online drug insert.

**Decision rationale:** The California Medical Treatment Utilization Schedule Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic and they recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. As Tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule chronic pain guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review failed to provide documentation the injured worker had moderate arthritis. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. There was documentation the injured worker was being monitored for aberrant drug behavior and side effects. However, there was a lack of documentation of objective improvement in function and an objective decrease in pain. Additionally, the request as submitted failed to indicate the dosage and frequency. The documentation indicated the injured worker had utilized the medication since at least 06/2014. Given the above and the lack of documentation, the request for Synapryn 10mg/1ml oral suspension 500ml is not medically necessary.

**Tabradol 1mg/ml oral suspension 250ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

**Decision rationale:** Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California Medical Treatment Utilization Schedule guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in

tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence based literature for the oral compounding of cyclobenzaprine and methanesulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. The clinical documentation submitted for review failed to provide documentation that the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation to support the necessity for an oral suspension. The request as submitted failed to indicate the dosage and frequency for the requested medication. Additionally, the documentation indicated the injured worker had utilized the medication since at least 06/2014. Given the above, and the lack of documentation, the request for Tabradol 1mg/ml oral suspension 250ml is not medically necessary.

**Deprizine 15mg/ml oral suspension 250ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Deprizine>.

**Decision rationale:** The California Medical Treatment Utilization Schedule Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine: Generic Name: ranitidine hydrochloride has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to indicate the injured worker had an inability to swallow or tolerate a pill. As this medication has not been found to be safe and effective per the Federal Drug Administration, this request would not be supported. Additionally, the request as submitted failed to indicate the dosage and frequency for the requested medication. The documentation indicated the injured worker had utilized the medication since at least 06/2014. The efficacy was not provided. The request is not medically necessary.

**Dicopanor (diphenhydramine) 5mg/ml oral suspension 150ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Insomnia Treatments and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Dicopanor>.

**Decision rationale:** The Official Disability Guidelines indicate that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. Per Drugs.com, Dicopan<sup>ol</sup> is diphenhydramine hydrochloride and it was noted this drug has not been found by the FDA to be safe and effective and the labeling was not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated that the injured worker had utilized the medication since at least 06/2014. There was a lack of documented efficacy. There was a lack of documentation indicating exceptional factors as this medication has not been found by the FDA to be safe and effective and labeling has not been approved per the FDA. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the dosage and frequency. Given the above, the request for Dicopan<sup>ol</sup> (diphenhydramine) 5mg/ml oral suspension 150ml is not medically necessary.

**Fanatrex (gabapentin) 25mg/ml oral suspension 420ml:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Fanatrex>.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. Per drugs.com, Fanatrex is an oral suspension of Gabapentin that has not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted review failed to provide the efficacy for the requested medication. There was a lack of documentation of exceptional factors. The documentation indicated the injured worker had utilized the medication since at least 06/2014. There was a lack of documentation indicating the injured worker had an inability to swallow a tablet or pill. The request as submitted failed to indicate the frequency and dosage for the requested medication. Given the above, the request for Fanatrex (gabapentin) 25mg/ml oral suspension 420ml is not medically necessary.

**MRI of the Right Shoulder:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 208-209. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 207-209.

**Decision rationale:** The ACOEM Guidelines indicate that special studies are not needed unless there has been a 4 to 6 week period of conservative care and observation that fails to improve symptoms. The primary criteria for ordering imaging studies include the emergence a red flag, physiologic evidence of tissue insult or neurovascular dysfunction, and a failure to progress in a strengthening program intended to avoid surgery as well as clarification of the anatomy prior to an invasive procedure. The clinical documentation submitted for review indicated the MRI was recommended. However, the rationale was not provided. There was a lack of documentation of a failure of conservative care. The injured worker was noted to have a positive Neer's test and reduced range of motion. However, given the above and the lack of documentation of rationale as well as documentation of a failure of conservative care, the request for MRI right shoulder is not medically necessary.

**Acupuncture treatments for the Right Shoulder and Wrist, x18:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Acupuncture Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines state that acupuncture is used as an option when pain medication is reduced or not tolerated and it is recommended as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. The time to produce functional improvement is 3 - 6 treatments and Acupuncture treatments may be extended if functional improvement is documented including either a clinically significant improvement in activities of daily living or a reduction in work restrictions. The clinical documentation submitted for review indicated the injured worker had previously undergone acupuncture treatments. There was a lack of documentation of a clinically significant improvement in activities of daily living or a reduction of work restrictions. Additionally, there was a lack of documentation indicating the quantity of sessions previously attended. Given the above and the lack of documentation, the request for acupuncture for the right shoulder and wrist is not medically necessary.

**Terocin patches, unknown quantity:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Lidocaine Page(s): 105, 111, 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:  
<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb>.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of

Anti-depressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov), Terocin patches are topical Lidocaine and Menthol. The clinical documentation submitted for review failed to provide documentation the injured worker had a trial and failure of an antidepressant and anticonvulsant. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommends. The request as submitted failed to indicate the frequency, quantity and strength for requested medication. Given the above, the request for Terocin patches, unknown quantity is not medically necessary.